

### **REMARKS**

Claims 7, 8 and 11-15 are pending in the present application. Claims 1-6, 9 and 10 have been previously cancelled without prejudice or disclaimer. Claim 15 has been withdrawn as being directed to non-elected subject matter.

Applicants, by previously canceling or amending any claims, make no admission as to the validity of any rejection made by the Examiner against any such claims. Applicants reserve the right to reassert any of the claims canceled and/or the original claim scope of any claim amended, in a continuing application.

Applicants note that the presently claimed subject matter is, as recited in independent claim 7, directed to a "patch-containing pouch, comprising: a multilayer film having a thickness of from 20 to 100  $\mu\text{m}$ , the multilayer film comprising an innermost layer having a polyacrylonitrile surface for contact with a patch, the patch comprising a pressure-sensitive adhesive layer laminated on at least one side of a support and a release film attached to the pressure-sensitive adhesive layer, the pressure-sensitive adhesive layer containing a drug represented by general formula (1) [Formula Omitted] or a pharmaceutically acceptable salt thereof, wherein R represents 2-isopropoxyethoxymethyl, carbamoylmethyl or 2-methoxyethyl." As recognizable to one of ordinary skill in the art by reading, the originally filed specification at, for example, paragraphs [0003], [0006], [0009], [0026] and [0051], among others, the polyacrylonitrile recited in claim 7 is a polyacrylonitrile homopolymer, and not a copolymer comprising polyacrylonitrile.

In view of the following, further and favorable consideration is respectfully requested.

- I. At page 3 of the Official Action, claims 7, 8, 11, and 12 have been rejected under 35 USC § 103(a) as being unpatentable over Kanios (US Patent No. 6,905,016) in view of JP 2003-303122 ("JP '122"), or vice versa JP '122 in view of Kanios et al.***

The Examiner asserts that it would have been obvious to provide a package for transdermal system comprising an innermost layer of acrylonitrile and outermost layer of polyethylene terephthalate as allegedly taught by Kanios to deliver bisoprolol in adhesive as allegedly taught by JP '122.

In view of the following, this rejection is respectfully traversed.

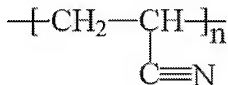
To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." See *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 at 417-418. Second, the proposed modification of

the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

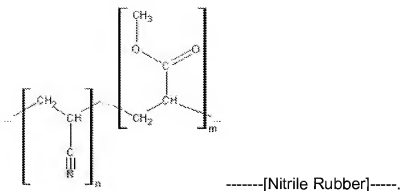
It is submitted that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, none of the cited references teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*. In addition, Applicants submit that the presently claimed subject matter is unexpectedly superior over the cited art for at least the reason that the claimed patch-containing pouches exhibit superior gas permeability and manageability.

Independent claim 7 is directed to a patch-containing pouch, comprising: a multilayer film having a thickness of from 20 to 100  $\mu\text{m}$ , the multilayer film comprising an innermost layer **having a polyacrylonitrile surface** for contact with a patch, the patch comprising a pressure-sensitive adhesive layer laminated on at least one side of a support and a release film attached to the pressure-sensitive adhesive layer, the pressure-sensitive adhesive layer containing a drug represented by general formula (1) [Formula Omitted] or a pharmaceutically acceptable salt thereof, wherein R represents 2-isopropoxyethoxymethyl, carbamoylmethyl or 2-methoxyethyl. Claims 8, 11 and 12 depend, either directly or indirectly, from claim 7.

In contrast, Kanios is directed to a propanalol containing patch packaged in a pouch having a total thickness of about 1000 to 6250  $\mu\text{m}$ . See Kanios, generally. In addition, Kanios is describes to pouches having an innermost layer with a surface that includes a Barex 210. See Kanios at column 6, line 33, which describes Barex 210 as the primary layer 11. As evidenced by the attached Barex 210 specification sheet, Barex 210 is an acrylonitrile-methyl acrylate copolymer, which is modified with rubber. However, Applicants submit that this is not the same as the claimed patch-containing pouch, which comprises a multilayer film that comprises an innermost layer **having a polyacrylonitrile surface**, i.e., a polyacrylonitrile homopolymer surface. As known by those skilled in the art, a polyacrylonitrile homopolymer is structurally different than a acrylonitrile-methyl acrylate copolymer or a polyacrylonitrile copolymer. As evidence of this, Applicants note that the chemical structure of an acrylonitrile homopolymer is:



In complete contrast, the chemical structure of Barex 210 consists of polyacrylonitrile-methyl acrylate copolymers modified by Nitrile Rubber, and is represented by the chemical structure shown below:



Thus, Applicants submit that Kanios does not teach or suggest an innermost layer having a polyacrylonitrile homopolymer.

In addition, JP '122 merely describes a bisoprolol containing patch. However, JP'122 does not teach or suggest a pouch for encasing the patch described therein, let alone a pouch as claimed.

Therefore, whether taken alone, or in combination, none of the cited references teach or suggest a patch-containing pouch, which comprises a multilayer film that comprises an innermost layer **having a polyacrylonitrile surface**, i.e., a polyacrylonitrile homopolymer surface.

As described at paragraph [0009] of the as-filed specification "...by using the pouch according to the present invention, it is possible to inhibit drug migration even with patches containing the drugs mentioned above, thus allowing a high drug content to be maintained in the patch even after prolonged storage." However, as set forth at paragraph [0003] of the originally filed specification, "...when the drug used is bisoprolol or a compound with a chemical skeletal structure similar thereto, it is not possible to prevent adhesion **even when using a film made of an ethylene/vinyl alcohol copolymer or acrylonitrile/methyl acrylate copolymer....**" (Emphasis

added). Therefore, it is submitted that the structure of the presently claimed patch-containing pouch, in particular, the use of an acrylonitrile homopolymer as the innermost surface of the pouch, results in the unexpectedly superior property of preventing migration of the drug/adhesion from the patch contained in the pouch.

Applicants note that *Kanios expressly teach away from the presently claimed subject matter* because Kanios require an acrylonitrile-methyl acrylate copolymer as the innermost surface of the pouch. In this regard, as discussed above, the use of an acrylonitrile-methyl acrylate copolymer inner surface will not prevent adhesion in the manner that the presently claimed pouch operates.

In addition, Applicants submit that the claimed subject matter is also non-obvious because the claimed patch-containing pouches exhibit superior gas permeability, which is derived from the combination of the structure of the claimed pouch, i.e., a pouch having an a surface for contact with the patch enclosed thereby which consists of polyacrylonitrile, the patch having the claimed structure and active ingredient. As evidence of this Applicants respectfully direct the Examiners attention to paragraph [0031] of the present specification, which provides that:

From the standpoint of gas permeability and manageability of the pouch, the thickness of the multilayer film 10a or 10b is preferably 20-100  $\mu\text{m}$ . ***A thickness of less than 20  $\mu\text{m}$  will lead to insufficient strength and may invite damage***, thus impairing the airtightness, ***while a thickness of greater than 100  $\mu\text{m}$  will impair the flexibility of the film***, possibly leading to poor manageability. (Emphasis Added).

Applicants respectfully submit that, in addition to not being obvious because every element is not taught or suggested by the cited art, the presently claimed subject matter is non-obvious due to unexpectedly superior gas permeability and

manageability exhibited.

In view of the foregoing, Applicants respectfully submit that, whether taken alone or in combination, nothing in the cited references render the presently claimed subject matter obvious within the meaning of 35 USC § 103. Accordingly, reconsideration and withdrawal of this rejection is respectfully submitted.

***II. At page 11 of the Official Action, claims 13 and 14 have been rejected under 35 USC § 103(a) as being unpatentable over Kanios (US Patent No. 6,905,016) in view of JP '122, as applied to claims 7, 8, 11 and 12 above, and in further view of JP 07-132946 ("JP '946").***

The Examiner asserts that it would have been obvious to add an aluminum foil layer to a multilaminate package having an innermost layer of acrylonitrile and outermost layer of terephthalate, as allegedly separately taught by Kanios, JP'122 and JP '946.

In view of the following, this rejection is respectfully traversed.

A brief outline of the relevant authority on obviousness is set forth above.

The presently claimed subject matter is also discussed in detail above with reference to independent claim 7. Applicants submit that claims 13 and 14 depend indirectly from claim 7.

In addition, each of Kanios and JP '122 are also discussed above.

As discussed above, whether taken alone or in combination, Kanios and JP '122 do not teach or suggest a patch-containing pouch, which comprises a multilayer film that comprises an innermost layer ***having a polyacrylonitrile surface***, i.e., a polyacrylonitrile homopolymer surface, as recited in claim 7. Additionally, Kanios teach away from the claimed subject matter since Kanios require an acrylonitrile-

methyl acrylate copolymer as the innermost surface of the pouch. Furthermore, the presently claimed patch containing pouches exhibit unexpectedly superior properties including, for example, reduced drug migration/adhesion from the patch to the pouch and superior gas permeability. The result of these unexpectedly superior properties are patch-containing pouches with superior storage stability with reduced drug loss as compared to similar patches that do not have an innermost surface consisting of polyacrylonitrile, i.e., a polyacrylonitrile homopolymer.

Applicants respectfully submit that JP '946 does not remedy the deficiencies of Kanios and JP '122. JP '946 is merely cited to show that aluminum may be utilized as a material in constructing housing material. However, like Kanios and JP '122, JP '946 also does not teach or suggest a patch-containing pouch, which comprises a multilayer film that comprises an innermost layer ***having a polyacrylonitrile surface***, i.e., a polyacrylonitrile homopolymer surface. Thus, whether taken alone or together, none of the cited references teach or suggest every element of the claimed subject matter, as required by *In re Wilson*.

In view of the foregoing, Applicants respectfully submit that, whether taken alone or in combination, nothing in the cited references render the presently claimed subject matter obvious within the meaning of 35 USC § 103. Accordingly, reconsideration and withdrawal of this rejection is respectfully submitted.



**CONCLUSION**

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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